

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-20 (canceled)

Claim 21 (new): A method of checking the leaktightness of a sealed container which holds a pharmaceutical active substance formulation in a chamber provided inside said container, the sealed container also holding a gas (the second gas) comprising the steps of a) acting upon the sealed container with a first gas which differs from the second gas enclosed within the container such that the increase in the quantity of the first gas inside the chamber can be analysed and b) opening the container and removing some of the gas which is located inside the chamber for the active substance formulation, for the purpose of qualitative, quantitative or both analysis, wherein both the acting and opening is carried out at a temperature of 0°C to 50°C.

Claim 22 (new): The method according to claim 21, characterised in that the container is a foil container which consists of at least one covering film and one base film which may in turn consist of one or more layers, the covering film and the base film being firmly joined together along their periphery.

Claim 23 (new): The method according to claim 22, characterised in that the foil container is a blister.

Claim 24 (new): The method according to claim 23, characterised in that the foil material for each of the films is selected, independently of one another, from the group comprising metal foils, plastic films or composite films, or it is a layer of paper.

Claim 25 (new): The method according to claim 24, characterised in that at least one of the films is an aluminium foil.

Claim 26 (new): The method according to claim 24, characterised in that at least one of the films consists of a material selected from the group comprising polyvinyl chloride, cycloolefin copolymer, polychlorotrifluoroethylene, polyethylene, polypropylene, polyethylene terephthalate, polycarbonates, polyesters, polyacrylates and/or polyamides.

Claim 27 (new): The method according to claim 21, characterised in that the container is a sealed, two-layer, bottle-like container with a rigid outer shell and an inner container mechanically attached to the outer shell only at certain points and able to collapse in on itself relative to the outer container.

Claim 28 (new): The method according to claim 27, characterised in that the container has been produced by a coextrusion process.

Claim 29 (new): The method according to claim 27, characterised in that the outer container consists of polypropylene and the inner container consists of polyethylene.

Claim 30 (new): The method according to claim 21, characterised in that the container is a sealed collapsible bag provided with a flange.

Claim 31 (new): The method according to claim 30, characterised in that the bag consists of a metal foil such as, for example, an aluminium foil a plastic film or both, or a plastic-coated metal foil.

Claim 32 (new): The method according to claim 30, characterised in that the bag is embedded in a metal sleeve.

Claim 33 (new): The method according to claim 21, characterised in that the action is carried out at a pressure difference between the interior of the container and its outer environment of 0.1 to 10 bar.

Claim 34 (new): The method according to claim 33, wherein the pressure difference is between 0.5 to 5 bar.

Claim 35 (new): The method according to claim 34, wherein the pressure difference is between 1 and 2 bar.

Claim 36 (new): The method according to claim 21, characterised in that the action is carried out by using permeation effects at a pressure difference of about zero between the interior of the container and the outer environment or diffusion or both with little or no pressure difference between the interior and exterior of the container.

Claim 37 (new): The method according to claim 21, characterised in that the gas used for the action is selected from the group comprising hydrogen, water vapour, noble gases such as helium, neon, argon, krypton, carbon dioxide, nitrogen, carbon monoxide, carbon-sulphur gases, sulphur dioxide, hydrogen sulphide, hydrocarbons such as methane or ethane, fluorohydrocarbons such as TG 134a or TG 227, or chlorofluorohydrocarbons.

Claim 38 (new): The method according to claim 37, characterized in that the gas used for the action is helium.

Application No.: 10/662,601
Amdt dated: September 2, 2004
Reply to Office action of July 6, 2004

Claim 39 (new): The method according to claim 21, characterised in that the opening and removal of the gas are carried out in a single step.